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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/630,166 | 07/30/2003 | Rajmani Tigunait | 521 P 049 | 7643 |
| 22508 | 7590 | 02/13/2008 | | |
| BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606 | | | EXAMINER | |
| | | | MELLER, MICHAEL V | |
| ART UNIT | | PAPER NUMBER | | |
| 1655 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/630,166 | Applicant(s) TIGUNAIT ET AL. |
| | Examiner Michael V. Meller | Art Unit 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 42-53 is/are pending in the application.
- 4a) Of the above claim(s) 44, 45, 51 and 52 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 42, 43, 46-50, 53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of the specific composition of water, zinc acetate dihydrate, hydrastine and an extract of grapefruit seed in the reply filed on 5/10/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

As such, claims 44, 45, 51 and 52 are withdrawn from further consideration by the examiner since they are not drawn to the specifically elected composition as noted above.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42, 43, 46-50, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. in view of Domingo et al.

Gelber teaches a medicinal composition containing zinc acetate, goldenseal extract (which as noted on col. 5, lines 30-40 that hydrastine comes from goldenseal thus hydrastine is in the goldenseal extract) and grapefruit extracts were combined together in the same formulation, see col. 5, lines 30-45, col. 7, lines 1-55, the tables, col. 12, lines 1-45. Note also that the composition can be in the form of a nasal spray which is taught as being an aqueous saline solution which clearly has water in it, see col. 12, lines 15-25.

Gelber does not explicitly teach that the zinc acetate is a dihydrate in the reference.

Domingo teaches that zinc acetate dihydrate is known to be used in medicinal formulations. Zinc acetate dihydrate is simply the salt of zinc acetate which is clearly known as taught by Domingo.

It would have been obvious for one of ordinary skill in the art to use the specific salt of zinc acetate, namely zinc acetate dihydrate, as taught by Domingo in the medical

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composition of Gelber since Domingo makes it clear that such salts are clearly known and clearly known to be used in pharmaceutical formulations, see abstract of Domingo.

Further, the result-effective adjustment in conventional working parameters (e.g., determining an appropriate salt of a specific compound, namely, zinc acetate dihydrate) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan especially in the fact that Domingo makes it clear that the salt of zinc acetate is well known and is used for pharmaceutical formulations.

Applicant argues that Gelber does not teach a nasal irrigation solution, but the claims are not limited to the intended use since they are product claims. Further, as noted by Gelber, suspensions are taught, see col. 12, lines 5-45, and aqueous solutions which clearly falls within "nasal irrigation solution". The intended use of this product carries no patentable weight. Applicant also argues that Gelber in examples 14 and 15 only teaches compositions directed to a nasal spray which requires ingredients which are not claimed. The claims are open since they use the language "comprising". Thus, they can include other ingredients. In example 14 it is clear that Gelber uses grapefruit seed and in table 7 it is also clear that zinc acetate and goldenseal extracts (which contain hydrastine as already noted on the record) are all contemplated for use in nasal sprays. Thus, all of the claimed ingredients are clearly contemplated to be used in Gelber. Since the solution is aqueous, water is also present. Thus, clearly meeting all of the claim limitations.

As already noted on the record, the specific amounts used of the ingredients is merely a matter of judicious selection and routine optimization.

Applicant finally argues that Domingo does not teach all of the ingredients, but this is a 35 USC 103 rejection and not a 35 USC 102 rejection, thus it does not have to contain all of the claimed elements.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/

Primary Examiner, Art Unit 1655